

## **REMARKS**

By this Amendment, claims 1, 5, and 6 have been amended and claims 9-15 have been cancelled without prejudice. Claims 1-8 are thus currently under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

As an initial matter, in the Office Action of September 10, 2008, the Examiner made several minor objections to the wording of claims 1, 5, and 6. These objections have now become moot by virtue of the present amendments, which comply with the Examiner's suggestions to overcome the objections to the claims. In particular, claim 1 has been rewritten to begin with an article, and claims 5 and 6 have been amended to correct a previous typographical error and insert a space between the terms "amino" and "acid." Accordingly, Applicants respectfully request that the objections to claims 1, 5, and 6 be withdrawn.

In the Office Action, the Examiner then rejected claims 1-4, 7, and 8 under 35 U.S.C. §112, second paragraph as being indefinite. In particular, the Examiner asserted that claim 1 is indefinite because the phrase "antibody Fab or scFv fragment" was unclear and because the phrase "characterized by the ability to mimic Her-2/neu tumor associated antigen" was not a positive recitation of the function of mimicking Her-2/neu. By virtue of the present amendments to claim 1, these rejections have now been rendered moot and, accordingly, Applicants respectfully traverse the rejections, insofar as applied to the claims as amended, and request that they be withdrawn.

Specifically, in accordance with the Examiner's suggestions in the Office Action, claim 1 has now been amended to include a hyphen after "Fab" and "scFv" to clarify that these terms refer to a fragment of an antibody, where the fragment is a Fab- or scFv- fragment. Further, by the present amendments, claim 1 has been amended to indicate that the human anti-idiotypic antibody Fab- or scFv-fragments described and claimed in the present application are each capable of mimicking Her-2/neu tumor associated antigen.

In the Office Action, the Examiner also rejected claims 1-4, 7, and 8 under 35 U.S.C. §112, first paragraph. In particular, the Examiner asserted that while the specification was enabling for anti-idiotypic antibody Fabs or scFvs that mimic Her-2/neu, such as the scFv40 comprising SEQ ID NO: 1 or scFv69 comprising SEQ ID NO: 2, the specification does not provide enablement for fragments of anti-idiotypic antibody Fabs or scFvs, or the fragments where only one CDR is defined. For the reasons set forth below, Applicants respectfully traverse this rejection, insofar as applied to claims as amended, and request that the rejection be withdrawn.

By virtue of the present amendments, claim 1 has now been amended to indicate that the Fab- or scFv-fragments refer to fragments comprising the sequences of CDR1H, CDR2H, CDR1L, and CDR2L, which are shared by scFv40 and scFv69, as well as the sequences of CDR3H and CDR3L of scFv40 or the sequences of CDR3H and CDR3L of scFv69. Support for these claim amendments can be found, in Figure 9, of the present application, which clearly demonstrates that the scFv40 and scFv69 fragments are comprised of distinct CDR1, CDR2, and CDR3 regions.

Further, by this amendment, Applicants have now amended the sequence listing and the specification accordingly to include the amino acid sequence of CDR1H, CDR1L, CDR2H, and CDR2L. Applicant thus state that in accordance with 37 C.F.R. §1.821(f) that the content of the paper sequence listing and the computer readable form are the same, and that in accordance with 37 C.F.R. §1.821(g), the enclosed sequence listing contains no new matter. A separate Statement is also attached hereto.

Accordingly, by the present amendments which include the attached sequence listing, every CDR of the claimed antibody fragment has been structurally defined and further corresponds to a CDR of a fragment which is demonstrated in the specification of the present application as being capable of mimicking Her-2/neu tumor associated antigen. For these reasons, Applicants thus submit that claims 1-4, 7, and 8 are in compliance with the enablement provisions of 35 U.S.C. §112, first paragraph, and thus further submit that the rejection of these claims is respectfully traversed and should be withdrawn.

Finally, in the Office Action of August 20, 2008, the Examiner made several rejections to the claims of the present application under 35 U.S.C. 103(a) as being unpatentable over Baral, et al. (Int. J. Cancer. 92: 88-95, 2001) in view of Fengtian, et al. (Chin. Med. Sci. J. 17(4): 215-219, 2002) or Tripathi, et al. (Molecular Immunology. 35: 853-863, 1998), and further in view of Marks, et al. (J. Mol. Biol. 222(3): 581-597, 1991), alone or in combination with Cho, et al. (Nature. 421: 756-760, 2003) or Todorovska, et al. (Journal of Immunological Methods. 248: 47-66, 2001). In particular, although the Examiner acknowledges that the cited references fail to teach or suggest an

anti-idiotypic Fab or scFv immunoglobulin, the Examiner has asserted that it would have been obvious to make a human scFv anti-idiotype immunoglobulin directed against an anti-Her2/neu antibody because anti-Her2 antibodies are known in the art, the use of a phage display for generating scFv immunoglobulins is known in the art, and because libraries for making the human scFv immunoglobulins are known in the art. For the reasons set forth below, Applicants submit that these rejections are respectfully traversed and should be withdrawn.

The claims of the present application, as amended, are directed toward antibody fragments comprised of specific CDR sequences including, in particular, the sequences of CDR3H and CDR3L of scFV40 or the sequences of CDR3H and CDR3L of scFv69. It is noted that antibody fragments that are comprised of the sequences of CDR3H and CDR3L are set forth in claims 2 and 3 of the present application, respectively, and, as the Examiner has acknowledged in the present Office Action, these fragments are not made obvious by the cited references. Indeed, it is the case that the cited references do not teach or suggest the particular sequences of CDR3H and CDR3L of scFV40 or the sequences of CDR3H and CDR3L of scFv69 that are described and claimed in the present application.

Accordingly, Applicants respectfully submit that the present invention is not rendered obvious by the cited references and that the claims of the present application, as amended, are clearly patentable over those references. Applicants thus submit that the Examiner's rejections on the basis of those references is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections, and has been placed in condition for allowance. Such action is respectfully requested.

Respectfully submitted,



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